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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,392	08/22/2001	Jeffrey T. Mason	001P0001	1-470

7590

01/21/2003

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/21/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

BEST AVAILABLE COPY

Office Action Summary

Application No.

09/935,392

Applicant(s)

MASON, JEFFREY T.

Examiner

Roz Ghafoorian

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 18 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-18, 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-10 and 25-26, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.4623330 to Laby et al, and further in view of U.S Patent No.5505707 to Manzie et al.

Laby teaches gas diffusion-limited controlled release devices. Laby teaches a medication delivery system comprising of an infusion pump, fluid storage chamber a displacement piston, an elastic member, a pump outlet. Laby however, is does not teach a bolus injector system or a drip chamber. Manzie discloses a tubing system with pump for delivering continues fluid flow or fluid bolus to a surgical site, which consists of a drip chamber and a bolus injector (Fig 2)

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined these systems, because according to Manzie this system will eliminate the inconvenience or awkwardness for the physician to adjust the clamp to control the fluid flow while also handling the surgical instrument. (Col.1, lines 45-50), furthermore a drip chamber will allow the caregiver an extra check point hence more control over the introduction of fluid into the patient, and as it is well known

Art Unit: 3763

control over fluid intake of a patient is crucial and if its not well controlled it may have devastating outcomes;

2. Claims 17-18 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.6247995 to Bryan, and further in view of U.S Patent No. Patent No.5505707 to Manzie et al.

Bryan teaches a bioluminescent novelty item. Bryan's apparatus comprises of infusion pump with 2 pump outlets, an elastic member, and two fluid storage chambers. Bryan, however, does not teach a bolus injector, two pumps, or two springs. Manzie discloses a tubing system with pump for delivering continues fluid flow or fluid bolus to a surgical site, which consists of a drip chamber and a bolus injector (Fig 2)

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have duplicated the pump and spring because the applicant has not disclosed that 2 separate pump and two separate springs can provide an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with one pump and spring, as described in Bryan because both apparatus perform the same function. *In re of Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) it would have been an obvious matter of design choice to modify Bryan to obtain the invention as specified in claim.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined these systems, because according to Manzie this system will eliminate the inconvenience or awkwardness for the physician

Art Unit: 3763

to adjust the clamp to control the fluid flow while also handling the surgical instrument.

(Col.1, lines 45-50)

Response to Arguments

3. Applicant's arguments filed 11-14-2002 have been fully considered but they are not persuasive.

a. The applicant alleges the motivation of the examiner is not proper because Manzie does not teach infusion pump therefore the drip chamber used in Manzie cannot be introduced to Laby's apparatus with proper motive. However simply because Manzie does not teach an infusion pump that does not mean the an apparatus with an infusion pump does not need additional control for fluid injection into a patient; any type of apparatus which is used for infusion of fluids in a patient would benefit from stricter control over fluid irrigation.

b. The applicant argues the drip chamber in Manzie is silent regarding the flow chamber reverting the dip stream to a continuance stream. However Manzie teaches an outlet tube 58 positioned beneath the flow restriction 33 in the drip chamber the drip chamber 32 separated form the flow restriction by a drip gap, wherein the outlet tube 58 is capable revert of the drip steam exiting the flow restriction to a reverted continuous stream. If the caregiver places pressure on the dip chamber 32 then a reverted continuous stream would exists due to the way Manie's apparatus.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S Patent No.6159188 to Laibovitz et al.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Application/Control Number: 09/935,392

Page 6

Art Unit: 3763

RG

January 13, 2003

A large, stylized handwritten signature consisting of the letters 'R' and 'G' in a cursive, looped script.

A handwritten signature in cursive script that reads 'Michael J. Hayes'.

MICHAEL J. HAYES
PRIMARY EXAMINER